

REMARKS

Reconsideration of the above-identified patent application is respectfully requested. Claims 1, 3 and 7-17 are pending in the subject application and have been examined on the merits.

In the Office Action, the Specification has been objected to for purportedly failing to provide proper antecedent basis for the claimed subject matter. Specifically, step "(a)" of independent claim 13 and claims 14-17 dependent upon it are purportedly lacking clear antecedent basis from the Specification. Applicants assert that support for the step "(a)" of claim 13 can be found in the specification at page 11 line 8 to page 12 line 23. Accordingly, withdrawal of the objection to the specification for failure to provide proper antecedent basis is respectfully requested.

In addition, claims 1, 3 and 7-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stovall (WO 99/04720, hereinafter "Stovall") in view of Murphy (WO 00/29553, hereinafter "Murphy").

Applicants respectfully traverse this rejection. For the reason set forth below, it is believed that claims 1, 3 and 7-17 are not rendered obvious by the cited prior art.

The presently claimed invention is directed to methods for repairing an intervertebral disc of a patient. The methods comprise forming at least one opening in the annulus fibrosis of the intervertebral disc, removing at least a portion of the nucleus pulposus through the opening and grafting a bioremodelable cultured connective tissue construct comprising an extracellular matrix layer and cultured fibroblasts (*e.g.*, page 2 line 15 to page 16 line 2).

Applicants' Claims Are Non-Obvious Over The Cited Prior Art

To establish a *prima facie* case of obviousness of a claimed invention, three basic criteria must me met:

- 1) There must be some suggestion or motivation, either in the reference itself, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference;
 - 2) There must be a reasonable expectation of success;
 - 3) The prior art reference (or references combined) must teach or suggest all of the claimed limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art.
- MPEP § 706.02(j).

Applicants respectfully submit that the Examiner's modification of Stovall with Murphy as proposed fail to meet the criteria (1) and (2) to establish a *prima facie* case of obviousness, thus withdrawal of this rejection is respectfully requested.

Stovall teaches and suggests a method for treating a ruptured intervertebral disc by aspirating all or part of a cell-containing gel from the disc, thereby reducing the nucleus pulposus volume; excising damaged tissue from the annulus fibrosus of the ruptured disc leaving a hole therein; covering the hole with a layer containing cells and injecting a cell-containing suspension (or aspirate, but not a tissue construct) into the disc through the annulus fibrosus to restore the nucleus pulposus volume (*e.g.*, page 2, lines 10-18 and Figure 2).

Murphy teaches and suggests an in vitro method for producing tissue constructs by stimulation of cells to produce an extracellular matrix (*e.g.*, page 1, lines 28-29). During the culture, the cells organize the secreted matrix molecules to form a three dimensional tissue-like

structure (e.g., page 18, lines 20-21). Thus, when fully formed, the Murphy constructs have a structure with bulk thickness fibrous matrix (e.g., page 18, lines 26-27).

There is no motivation or suggestion to combine Stovall with Murphy in the manner proposed by the Office Action (e.g., to inject the cell-containing suspension of Stovall with the fibrous structure of Murphy).

As an initial matter, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no motivation to make the proposed modification. MPEP § 2143.01. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). That is, the structured tissue constructs of Murphy cannot be injected into the herniated disk through the annulus fibrosus as taught by Stovall because it would obstruct the injecting device due to its bulk thickness. Further, the attempt to modify Stovall with the tissue cell constructs of Murphy would render Stovall inoperable for its intended purpose to restore the volume of the nucleus pulposus. In view of the foregoing, Applicants maintain that there is no motivation to combine the teachings of Stovall with those of Murphy as proposed in the Office Action.

In addition, Applicants assert there is no reasonable expectation of success for the suggested modification. MPEP § 2143.02. As set forth above, the tissue constructs of Murphy are not the cell-containing suspensions of Stovall, but rather are bulky tissue-like structures which cannot be injected using the procedures taught by Stovall. As such, there is no reasonable expectation of success to modify Stovall with Murphy as proposed by the Office Action.

Finally, the mere fact that the references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. MPEP § 2143.01. In other words, the mere fact that the structured tissue constructs of Murphy could be used to cover the hole of the ruptured disk as taught by Stovall is

not sufficient to sustain a *prima facie* case of obviousness, because the suggestion or motivation to modify the reference must be found in the reference itself without the use of impermissible hindsight.

Therefore, for the reasons set forth above, Applicants respectfully request that the rejection of claims 1, 3 and 7-17 as being unpatentable over Stovall in view of Murphy under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

In light of the foregoing, the application is now believed to be in proper condition for allowance and a Notice to that effect is respectfully requested. If this *Response* does not otherwise result in the issue of such Notice, the Examiner is respectfully invited to contact the Applicants' undersigned counsel for an interview.

No extra fee is believed due. However, if any additional fees are necessary, the Director is hereby authorized to charge such fees to Deposit Account No. 50-0540.

Furthermore, Applicants are not aware of any prior art that has all of the elements of the claim or which in proper combination with other prior art would provide all of the elements of the claim.

Respectfully submitted,

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